

§ 315.1

16 CFR Ch. I (1–1–08 Edition)

315.7 Content of advertisements and other representations.

315.8 Prohibition of certain waivers.

315.9 Enforcement.

315.10 Severability.

315.11 Effect on state and local laws.

AUTHORITY: Pub. L. 108–164, secs. 1–12; 117 Stat. 2024 (15 U.S.C. 7601–7610).

SOURCE: 69 FR 40508, July 2, 2004, unless otherwise noted.

§ 315.1 Scope of regulations in this part.

This part, which shall be called the “Contact Lens Rule,” implements the Fairness to Contact Lens Consumers Act, codified at 15 U.S.C. 7601–7610, which requires that rules be issued to address the release, verification, and sale of contact lens prescriptions. This part specifically governs contact lens prescriptions and related issues. Part 456 of Title 16 governs the availability of eyeglass prescriptions and related issues (the Ophthalmic Practice Rules (Eyeglass Rule)).

§ 315.2 Definitions.

For purposes of this part, the following definitions shall apply:

Business hour means an hour between 9 a.m. and 5 p.m., during a weekday (Monday through Friday), excluding Federal holidays. “Business hour” also may include, at the seller’s option, a prescriber’s regular business hours on Saturdays, provided that the seller has actual knowledge of these hours. “Business hour” shall be determined based on the time zone of the prescriber.

“Eight (8) business hours” shall be calculated from the time the prescriber receives the prescription verification information from the seller, and shall conclude when eight (8) business hours have elapsed. For verification requests received by a prescriber during non-business hours, the calculation of “eight (8) business hours” shall begin at 9 a.m. on the next weekday that is not a Federal holiday or, if applicable, on Saturday at the beginning of the prescriber’s actual business hours.

Commission means the Federal Trade Commission.

Contact lens means any contact lens for which State or Federal law requires a prescription.

Contact lens fitting means the process that begins after an initial eye examination for contact lenses and ends when a successful fit has been achieved or, in the case of a renewal prescription, ends when the prescriber determines that no change in the existing prescription is required, and such term may include:

(1) An examination to determine lens specifications;

(2) Except in the case of a renewal of a contact lens prescription, an initial evaluation of the fit of the contact lens on the eye; and

(3) Medically necessary follow-up examinations.

Contact lens prescription means a prescription, issued in accordance with State and Federal law, that contains sufficient information for the complete and accurate filling of a prescription for contact lenses, including the following:

(1) The name of the patient;

(2) The date of examination;

(3) The issue date and expiration date of prescription;

(4) The name, postal address, telephone number, and facsimile telephone number of prescriber;

(5) The power, material or manufacturer or both of the prescribed contact lens;

(6) The base curve or appropriate designation of the prescribed contact lens;

(7) The diameter, when appropriate, of the prescribed contact lens; and

(8) In the case of a private label contact lens, the name of the manufacturer, trade name of the private label brand, and, if applicable, trade name of equivalent brand name.

Direct communication means completed communication by telephone, facsimile, or electronic mail.

Issue date means the date on which the patient receives a copy of the prescription at the completion of a contact lens fitting.

Ophthalmic goods are contact lenses, eyeglasses, or any component of eyeglasses.

Ophthalmic services are the measuring, fitting, and adjusting of ophthalmic goods subsequent to an eye examination.